IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

ARNOLD W. WEBSTER, *et al.*,	)	
Plaintiffs,	)	
v.	)	**Civil Action No. 01-00928 (ESH)**
PACESETTER, INC.	)	
Defendant.	)	

MEMORANDUM OPINION

This case presents one question: does Section 360k of the Medical Device Amendments of 1976, 21 U.S.C. § 360c *et. seq.* ("MDA"), to the Food, Drug and Cosmetic Act, 21 U.S.C. § 301 *et. seq.*, as amended ("FDCA"), preempt plaintiffs' common-law claims? While the issue can be stated simply, its resolution is far from straightforward. Although the Supreme Court in Medtronic, Inc. v. Lohr, 518 U.S. 470 (1996), found that there was no preemption for Class III medical devices that only receive Section 510(k) premarket notification review by the Food and Drug Administration ("FDA"), it left open the question whether FDA approval of a premarket approval application for a Class III device would constitute imposition of a "federal requirement" within the meaning of Section 360k of the MDA, and therefore preempt a plaintiff's state law tort claims. Following this decision by a fractured Court, the circuit courts have split when considering Class III devices that have received FDA

premarket approval, with the Fifth, Sixth, and Seventh Circuits holding in favor of preemption,[1/] and the Eleventh Circuit ruling against preemption.[2/] Although there are substantial arguments on both sides of the debate, this Court finds the reasoning of the Eleventh Circuit to be more persuasive and more faithful to Congress's intent in enacting the MDA and the rationale of the Lohr majority. Therefore, defendant's motion for summary judgment will be denied.

BACKGROUND

Daniel W. Webster had a history of heart trouble described as sinoatrial node dysfunction. On July 24, 1998, to stabilize his heart, plaintiff underwent an operation to implant a cardiac pacing system, consisting of three components: the TRILOGY DR+ Implantable Pulse Generator, model no. 2360L (the "pacemaker"), a TENDRIL DX Permanent Pacemaker Electrode, Atrial Lead, model no. 1388TC (the "atrial lead"), and a Passive PLUS DX Permanent Pacemaker Electrode, Ventricular Lead, model no. 1346T (the "ventricular lead"). All three components, the pacemaker and the two

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[1/] Martin v. Medtronic, Inc., 254 F.3d 573 (5th Cir. 2001); Kemp v. Medtronic, Inc., 231 F.3d 216 (6th Cir. 2000); Mitchell v. Collagen Corp., 126 F.3d 902 (7th Cir. 1997).

[2/] Goodlin v. Medtronic, Inc., 167 F.3d 1367 (11th Cir. 1999). An Eighth Circuit panel has also decided against preemption, Brooks v. Howmedica, Inc., 236 F.3d 956 (8th Cir. 2001), on the grounds that there is no conflict between federal and state requirements, but the decision has been vacated pending rehearing en banc, 246 F.3d 1149 (8th Cir. 2001). Prior to the Supreme Court's opinion in Lohr, the Ninth Circuit also ruled against preemption, focusing on issues of statutory interpretation and the intended scope of Section 360k. Kennedy v. Collagen Corp., 67 F.3d 1453 (9th Cir. 1995). Finally, the Tenth Circuit focused not on the existence of a federal "requirement," but on the generality of state common law claims to hold against preemption. Oja v. Howmedica, Inc., 111 F.3d 782 (10th Cir. 1997) (holding that in a case involving a Class II medical device state common-law claims of negligent failure to warn and negligent manufacture were not state requirements developed "with respect to" medical devices and therefore not preempted under Lohr).

lead wires, were manufactured by Pacesetter, Inc. After a post-surgery diagnostic examination, plaintiff was released with no complications from the Washington Hospital Center in Washington, D.C.

On August 5, 1998, plaintiff became weak and dizzy while riding in a car. He was rushed to an emergency room at the Lady of Lourdes Medical Center in Camden, New Jersey. After review of a CAT scan and echocardiogram, plaintiff's doctors concluded that the atrial lead had perforated the atrial chamber of his heart and diagnosed plaintiff with cardiac tamponade[3/] caused by a perforation of the heart wall. Plaintiff underwent a procedure known as median sternotomy and the perforation was repaired. On August 13, 1998, plaintiff was discharged from the hospital.

On April 2, 2001, Daniel W. Webster and his wife, Irene L. Webster, filed a complaint in the Superior Court for District of Columbia, alleging state law claims of strict liability; negligent warnings, design, manufacture, and follow-up evaluation; breach of warranty; and fraud and deceit on the part of Pacesetter, Inc. with respect to its atrial lead. Defendant filed a Notice of Removal on April 30, 2001, and the case was subsequently removed to this Court. On July 20, 2001, defendant filed a motion to dismiss or, in the alternative, for summary judgment. Defendant argues that the MDA expressly preempts plaintiffs' state law tort claims. In the alternative, defendant argues that plaintiffs' claims are impliedly preempted by the MDA. In order to address these arguments, the Court must first consider the MDA and the regulations promulgated thereunder, as well as the Supreme Court's seminal case in this area of the law -- Medtronic, Inc. v. Lohr.

[3/] According to a medical affidavit submitted by defendant, cardiac tamponade is a "condition where the fluid in the pericardial sack compresses the heart limiting its ability to fill with blood and hence, compromising the ability of the heart to pump blood." (Levine Aff. ¶ 9.)

LEGAL ANALYSIS

I. The PMA Process

In 1976, Congress passed the MDA in response to public concern regarding the safety and efficacy of medical devices, most notably the Dalkon Shield intrauterine device. The MDA confers broad regulatory authority over medical devices on the FDA and establishes a regulatory framework that classifies devices by the degree of risk posed to the public, subjecting devices that pose the greatest risk to the most exacting level of FDA scrutiny. Class III devices, which are considered to pose the greatest risk to the public, consist of those devices which "present[] a potential unreasonable risk of illness or injury" or are "purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health." 21 U.S.C. § 360c(a)(1)(C). Such devices are therefore subject to the most stringent level of regulation. Id.

Before a Class III device can be made publicly available, the manufacturer must submit its product to the FDA for premarket approval (the "PMA" process), and the FDA must conclude that it has received "reasonable assurance of [the device's] safety and effectiveness." Id. The PMA process is a rigorous and "time-consuming inquiry into the risks and efficacy of each device." Buckman Co. v. Plaintiff's Legal Comm., 121 S. Ct. 1012, 1017 (2001). PMA applicants must submit detailed information pertaining to the device, including all studies, reports, and other publications regarding its safety and efficacy, its component parts and functions, and the processes necessary to manufacture and package the device, as well as samples of the device, its labeling, and packaging. 21 U.S.C.§ 360e(c)(1); 21 C.F.R. § 814. The FDA reviews the submitted materials for an average of 1200 hours

before either approving or disapproving the application. See Lohr, 518 U.S. at 477 (citation omitted). The FDA may also advise a manufacturer of deficiencies in the PMA application and the measures necessary to render the application acceptable, including additional research. See 21 U.S.C. § 360e(d)(2). Once the FDA approves a PMA application, the medical device manufacturer may not change the labeling, design, or manufacture of an approved device in any way that would affect safety or effectiveness without submitting a PMA Supplement. See 21 C.F.R. §§ 814.39, 814.80. Changes unrelated to safety or effectiveness, however, may be made without pre-approval.

The atrial lead at issue in this case was subject to this extensive review as a Class III device under the MDA. On May 10, 1996, defendant submitted its PMA application for approval by the FDA. On June 20, 1997, the FDA approved defendant's application for the atrial lead by issuing a letter entitled "Conditions of Approval." (Def.'s Mot. at 6; Telep Aff., Ex. A.)

II. Express Preemption

To ensure national uniformity in the regulation of medical devices, the MDA expressly provides for preemption of certain state requirements:

> [N]o State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement –
> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C. § 360k(a). The provision is straightforward, although its interpretation and application have proved otherwise: Section 360k preempts any state law "requirement" that "relates to [] safety or

effectiveness" and is "different from, or in addition to" any federal "requirement" applicable to a medical device. Id. The FDA has promulgated regulations implementing this provision, which provide for preemption when the FDA has established "specific counterpart regulations" or other "specific requirements applicable to a particular device." See 21 C.F.R. § 808.1(d).

Under the Supremacy Clause of the United States Constitution, state laws that conflict with federal laws are simply without effect. See Cipollone v. Liggett Group, Inc., 505 U.S. 504, 516 (1992) (citation omitted). The Court's preemption analysis must be guided by two basic principles: first, there is a presumption against federal preemption of state regulation, and second, the "analysis of the scope of [a] statute's preemption is guided by . . . [the principle] that '[t]he purpose of Congress is the ultimate touchstone' in every pre-emption case." Lohr, 518 U.S. at 485 (quoting Retail Clerks Int'l Ass'n, Local 1625, AFL-CIO v. Schermerhorn, 375 U.S. 96, 103 (1963)); accord Cipollone, 505 U.S. at 516.

A. Lohr and Its Progeny

In its divided opinion in Medtronic, Inc. v. Lohr, the Supreme Court interpreted and applied Section 360k, holding that a less stringent form of MDA regulatory review did not preempt state common-law claims. Lohr concerned claims against the manufacturer of a failed pacemaker, a Class III medical device, which had reached the market by means of FDA approval under the Section 510(k) premarket notification process,[4/] an exception to the PMA process. Under the Section 510(k)

[4/]This process refers to the requirements set forth in 21 U.S.C. § 360(k); Section 510(k) refers to the number of the section in the original MDA legislation. See Lohr, 518 U.S. at 478.

process, if the FDA concludes on the basis of a manufacturer's premarket notification that the applicant's Class III medical device is "substantially equivalent" to a pre-existing device, the MDA permits marketing of the device without further regulatory analysis. 21 U.S.C. § 360e(b)(1)(B). In Lohr, a majority of the Court concluded that the plaintiff's negligence and strict liability claims, alleging defective design, manufacture and labeling of the medical device, were not preempted by the Section 510(k) notification and review process. 518 U.S. at 503. Because Justice Breyer joined only parts of the Court's plurality opinion authored by Justice Stevens, the analysis underlying the Lohr opinion has proven difficult to interpret and apply in the PMA context. See, e.g., Martin, 254 F.3d at 579, 581-82. In particular, Justice Breyer joined in Parts I through III and V of the plurality's opinion, but declined to join Part IV as irrelevant and Part VI because it underestimated the number of cases in which preemption of common-law claims might occur. Lohr, 518 U.S. at 508. Justice O'Connor, joined by the Chief Justice and Justices Scalia and Thomas, dissented on the grounds that MDA regulation of manufacturing and labeling imposed requirements preempting state common-law claims. Id. at 513-14. However, the Court was unanimous in its finding that plaintiffs' defective design claim was not preempted by the Section 510(k) process, which evaluates only "substantial equivalency." Id. at 513.

Despite these differences, a majority did emerge with respect to a number of issues in Lohr. Citing federalism concerns and the "historic primacy" of state regulation of health and safety, the Court made clear in Part III of its opinion that state police powers would not be preempted "'unless that was the clear and manifest purpose of Congress.'" Lohr, 518 U.S. at 485 (quoting Rice v. Sante Fe Elevator Corp., 331 U.S. 218, 230 (1947)). The Court further explained that this presumption against

preemption would apply to a determination of whether Congress intended preemption at all as well as to "support a narrow interpretation of such an express command." Id. The Court also indicated that the scope of the preemption provision must be drawn from an understanding of congressional purpose, to be derived from the language of the statute, its structure, and the surrounding regulatory framework. Id. at 485-86.

In Part V of its opinion, also joined by a majority, the Lohr Court read Section 360k, alongside an FDA regulation regarding the scope of MDA preemption, to ascertain the meaning of the term "requirement." As an initial matter, the Court noted that in most cases MDA preemption arises "only to the extent that the FDA has promulgated a relevant federal 'requirement.'" 518 U.S. at 496. To understand the term "requirement," the Lohr Court turned to the FDA implementing regulation, which provides for preemption only when the agency has established "'specific counterpart regulations or . . . other specific requirements applicable to a particular device.'" Id. at 498 (quoting 21 C.F.R. § 808.1(d)). Significantly, the majority held that this definition did not encompass MDA labeling regulations requiring inclusion of information regarding, inter alia, relevant hazards, contraindications, side effects, and precautions; neither did it include the MDA's "Good Manufacturing Practices" ("GMP's"), with which a manufacturer must comply. Id. at 501. Because these regulations were too general in scope and not applicable to the specific device in question, they had no preemptive effect.[5/]

[5/] As observed by the Court:

> The generality of those requirements make this quite unlike a case in which the Federal Government has weighed the competing interests relevant to the particular requirement in question, reached an unambiguous conclusion about how those competing considerations should be resolved in a particular case or set of cases, and implemented

Id. Similarly, a majority found that state common-law requirements were not specific to a medical device, and as such, were "general obligations" that were "no more a threat to federal requirements than would be a state-law duty to comply with local fire prevention regulations and zoning codes, or to use due care in the training and supervision of a work force." Id. 501-02. Finally, the majority agreed that Section 510(k) review and premarket approval did not result in preemption of state common-law claims. See id. at 492-502.

No majority emerged with respect to a number of questions, including how often MDA regulatory review would preempt state common-law causes of action. In Part VI of the plurality opinion, Justice Stevens, writing for four members of the Court, suggested that preemption of common-law duties would be "rare." Id. at 502-03. Four Justices agreed with the FDA's interpretation of Section 360k, as requiring "device specificity" in state law before preemption would be appropriate. Id. That is, a state law must have "'the effect of establishing a substantive requirement for a specific device'" before the preemption provision would apply. Id. at 503 (quoting 21 C.F.R. § 808.1(d)(6)(ii)). Justice Breyer declined to join Part VI because he believed that the MDA might preempt state common-law claims more frequently than indicated by the plurality. Id. at 508.

However, it is not clear that Justice Breyer disagreed with the plurality to any significant degree.

> that conclusion via a specific mandate on manufacturers or producers. Rather, the federal requirements reflect important but entirely generic concerns about device regulation generally, not the sort of concerns regarding a specific device or field of device regulation that the statute or regulations were designed to protect from potentially contradictory state requirements."

Lohr, 518 U.S. at 501.

As an example of an MDA requirement that would preempt a common-law claim, Justice Breyer offered the following: "a federal MDA regulation [that] requires a 2-inch wire" would preempt a state agency regulation that required a 1-inch wire, as well as a "state-law tort action that premises liability upon the defendant manufacturer's failure to use a 1-inch wire." Id. at 504. As Justice Breyer noted, his example is not necessarily inconsistent with the plurality opinion. Id. at 505. Furthermore, his concurrence suggests that a significant degree of specificity in the federal regulation is necessary to fall within the preemptive reach of Section 360k. According to Justice Breyer, the MDA demands preemption only when there are "'*specific* [federal] requirements applicable to a particular device.'" Id. at 506 (quoting 21 C.F.R. § 808.1(d) (emphasis added)).

The circuits remain divided as to whether FDA approval under the PMA process preempts state common-law claims. A majority of courts have found preemption. See, e.g., Martin v. Medtronic, Inc., 254 F.3d 573 (5th Cir. 2001); Kemp v. Medtronic, Inc., 231 F.3d 216 (6th Cir. 2000); Mitchell v. Collagen Corp., 126 F.3d 902 (7th Cir. 1997). Most recently in Martin v. Medtronic, Inc., the Fifth Circuit reaffirmed an earlier holding that state tort suits can constitute specific requirements related to device safety and effectiveness for the purposes of Section 360k preemption, and that "the PMA process imposed specific federal requirements as to labeling, manufacturing, and design for the purposes of preemption." 254 F.3d at 581, 583. The court concluded that FDA approval imposed device-specific "requirements" because the PMA process is "specifically focused on safety" and requires review of "considerations specific to the device," including components, manufacture, and labeling. Id. at 584. The court did not elucidate the precise requirements imposed on the pacemaker at issue except to indicate that "[t]he design of the lead, the labeling on the lead, and the

manner of manufacturing of the lead were all submitted to the FDA in great detail and approved by the FDA in the PMA process." Id. at 584-85. For the Martin court, this was sufficient to preempt tort claims for failure to warn, inadequate labeling, and defective design.

Similarly, the Sixth Circuit, in Kemp v. Medtronic, Inc., and the Seventh Circuit, in Mitchell v. Collagen Corp., concluded that the PMA process confers specific approval on a medical device's "'design, testing, intended use, manufacturing methods, performance standards and labeling.'" Kemp, 231 F.3d at 226 (quoting Mitchell, 126 F.3d at 913). The Sixth Circuit identified the "totality of the [device's] design, manufacturing processes, and labeling – when coupled with the prohibition against modifying them" as the "specific federal requirement" given preemptive effect under the MDA. Id. at 228. The Seventh Circuit held that the PMA process constituted a "specific federal regulation" of medical devices, as well as a "specific federal interest" for preemption purposes. Mitchell, 126 F.3d at 911. As did the Fifth Circuit, these courts relied on the rigor and purpose of the PMA review process to find preemption. See Kemp, 231 F.3d at 227; Mitchell, 126 F.3d at 911.[6/]

Lining up on the other side, a minority of courts have held against preemption. See note 2,

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[6/] The Sixth Circuit also expressed the concern, echoed by defendant (Def.'s Mot. at 26-27), that any other conclusion would render Section 360k meaningless because approval pursuant to the PMA process would never result in preemption. See Kemp, 231 F.3d at 227. However, this conclusion rests on a misreading of Section 360k. The PMA process fails to preempt state law because it does not impose sufficiently specific requirements, not because Section 360k is without application. Section 360k would confer preemptive effect whenever the FDA chose to promulgate specific regulations or other specific requirements and a state counterpart regulation conflicted therewith. See discussion at pp. 13-16, infra; see also Lohr, 518 U.S. at 504 (federal regulation requiring 2-inch wire would preempt state counterpart requiring 1-inch wire) (Breyer, J., concurring).

supra.[7] The leading case for this position is Goodlin v. Medtronic, Inc., 167 F.3d 1367 (11th Cir. 1999). Focusing on the language of Section 360k and the FDA's implementing regulations, the Eleventh Circuit held that the PMA process did not impose specific federal requirements. 167 F.3d at 1375. Consistent with Lohr, the court relied on FDA regulations interpreting Section 360k to limit the preemptive scope of the MDA to include "only 'specific counterpart regulations' or 'specific requirements' that apply to 'a particular device.'" Id. at 1372 (quoting 21 C.F.R. § 808.1(d)). Therefore, the term "requirement" in Section 360k refers to the imposition of some "ascertainable condition." Id. at 1374. The court then evaluated the PMA process, concluding that neither FDA review nor approval imposes any "ascertainable requirement" on a device. Id. at 1375. The court noted that the FDA issues "no regulation, order, or any other statement of its substantive benchmark,"[8] and PMA approval does not provide "any indication of what (if any) specific substantive requirements the FDA may have applied to reach that result." Id. Thus, government permission to market a device does not fit within the preemption provision, for it is not a requirement. Id. The Goodlin court went on to note that this interpretation was consistent with the statutory scheme as a whole and other indicia of congressional intent.[9] Id. at 1378-80.

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[7] See also Lakie v. Smithkline Beecham, 965 F. Supp. 49 (D.D.C. 1997); Haidak v. Collagen Corp., 67 F. Supp. 2d 21 (D. Mass. 1999).

[8] Defendant singles out this statement for criticism, arguing that it is erroneous in "light of actual practice." (Def.'s Mot. at 24 n.7). However, defendant admits that the FDA did not "establish design, manufacturing, labeling, and performance standards for the device." (Id.) This is, of course, exactly what would be necessary for the FDA to impose a "specific requirement" on a device manufacturer. See discussion at pp. 13-16, infra.

[9] In a pre-Lohr case, the Ninth Circuit employed a similar approach, focusing on statutory interpretation and the intended scope of Section 360k, and concluded that the PMA process did not

The substantive split among the circuit courts mirrors a methodological difference: the majority focus on the rigor of the PMA process and often restrictive post-approval conditions, whereas the minority focus on congressional intent as expressed in the statute. Because congressional purpose is the "'ultimate touchstone'" of federal preemption analysis, Lohr, 518 U.S. at 485 (citation omitted), this Court finds that the minority's focus on the text of Section 360k is the preferable approach.

B. Preemptive Effect of PMA Approval

The Lohr Court establishes the test for applying Section 360k to determine MDA preemption: a court must undertake "a careful comparison between the allegedly pre-empting federal requirement and the allegedly pre-empted state requirement to determine whether they fall within the intended pre-emptive scope of the statute and regulations." Id. at 500. Thus, this Court must consider whether (1) through the PMA process the FDA establishes specific federal "requirements" applicable to the Pacesetter atrial lead; and (2) what, if any, federal requirements have been established.

Both the language of Section 360k and the FDA regulation implementing that provision favor the conclusion that the PMA review process does not amount to a specific federal requirement meriting

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preempt state common-law claims. Kennedy v. Collagen Corp., 67 F.3d 1453 (9th Cir. 1995), *rev'd on other grounds after remand*, 161 F.3d 1226 (9th Cir. 1998). Defendant claims that another Ninth Circuit panel backpedaled from this decision, finding for MDA preemption in Papike v. Tambrands Inc., 107 F.3d 737 (9th Cir. 1997). Defendant is wrong. Papike is not inconsistent with the panel decision in Kennedy. In fact, Papike provides clear evidence of FDA authority to promulgate specific "requirements." In Papike, the court considered the preemptive effect of FDA regulations, 21 C.F.R. § 801.430, regarding the substantive content of warnings on tampon packaging. In finding for preemption, the court noted that the regulation was "not only device-specific (tampons), but also disease-specific [Toxic Shock Syndrome]." Papike, 107 F.3d at 740. The PMA process is obviously far more general than that regulation; thus, Papike does not undermine the reasoning of Kennedy.

preemptive effect. The choice of language in Section 360k is instructive: as noted by the Eleventh Circuit, the term "requirement" suggests that FDA imposition of an "identifiable precondition" is necessary for preemption.[10/] Goodlin, 167 F.3d at 1374. The FDA implementing regulation also limits preemptive effect to "specific counterpart regulations" or a "specific requirement." 21 C.F.R. § 808.1(d). Thus, both the statutory language and the regulation demonstrate that preemption under Section 360k requires some affirmative prescriptive action by the FDA, i.e., the agency must promulgate an ascertainable precondition to regulatory approval. Goodlin, 167 F.3d at 1374. Moreover, this interpretation is entirely consistent with Justice Breyer's hypothetical, which posits an FDA regulation mandating the use of two-inch wires.

Defendant argues, nonetheless, that FDA approval demands preemption because the rigor of the process and the purposes of review result in the imposition of sufficiently specific requirements. (Def.'s Mot. at 22-28.) The FDA conducts an analysis of the risks and benefits specific to a particular device, and defendant argues, that approval therefore imposes specific requirements for the purposes of Section 360k. (Def.'s Mot. at 24). In support of this argument, defendant notes that the FDA has the

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[10/] As a plurality in Lohr noted, Congress chose the term "requirement," as opposed to "remedy," 518 U.S. at 487, suggesting that Congress did not intend to confer blanket preemption under the MDA. Moreover, defendant's proffered interpretation would foreclose judicial recourse to persons injured by approved medical devices by preempting such claims, thereby reading "requirement" as broadly as "remedy," and "having the perverse effect of granting complete immunity from design defect liability to an entire industry that, in the judgment of Congress, needed more stringent regulation in order 'to provide for the safety and effectiveness of medical devices intended for human use,' 90 Stat. 539 (preamble to Act)." Lohr, 518 U.S. at 487 (plurality opinion). This result, as noted by the plurality, could hardly have been intended, since "[i]t is, to say the least, 'difficult to believe that Congress would, without comment, remove all means of judicial recourse for those injured by illegal conduct.'" Id. (citation omitted). See also Goldin, 167 F.3d at 1380-81 & n.22.

authority to impose conditions on PMA-approved devices and to forbid, as it did here, the manufacturer from making any changes without approval to a device's design, components, manufacturing, or labeling that might affect safety or effectiveness.[11/] (Def's Mot. at 6, 24.)

However, while PMA approval is obviously device-specific, it is otherwise too general to permit identification of any specific requirements. See, e.g., Goodlin, 167 F.3d at 1374-75 (bemoaning "inability to ascertain any such identifiable requirement from the FDA's approval" of the pacemaker lead at issue). FDA's approval of defendant's atrial lead provides no indication of any requirements related to the safety or effectiveness of the device in question. The FDA's letter of approval of the atrial lead application is framed in general terms with respect to both design and labeling. (Def.'s Mot., Ex. 3A). Although the approval bars device changes related to safety or effectiveness absent approval, the agency did not identify specific alterations to design or labeling that would or would not be permitted. In fact, defendant altered the design of the atrial lead without FDA approval. (Telep Aff. ¶ 13.) The determination of what is related to safety and effectiveness is not set forth in the FDA approval letter, but is left to the manufacturer's own determination. Thus, the PMA does not impose any "identifiable precondition" applicable to the device. Goodlin, 167 F.3d at 1374.

Furthermore, neither the MDA nor the PMA process prescribes design specifications. The absence of such prescriptive specification was a significant consideration for the Lohr Court, a majority of which concluded that Section 510(k) review does "not 'require' [defendant's] pacemaker to take

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[11/] The FDA does permit certain "labeling, quality control, and manufacturing changes which would 'enhance[] the safety of the device or the safety in the use of the device' without prior approval. Lohr, 518 U.S. at 497 n.16 (quoting 21 C.F.R. §§ 814.39(d)(1), (2)).

any particular form for any particular reason." Id. at 493. The materials, components, manufacturing process, design, and labeling of a device are chosen by the manufacturer, not the FDA. Additionally, as defendant's own experience proves, manufacturers may make changes without FDA approval, so long as the changes are unrelated to safety and effectiveness. Furthermore, FDA review does not appear to entail consideration of alternative designs that might make the device safer. See Goodlin, 167 F.3d at 1369-70 (discussing PMA process). Neither does the FDA suggest design changes in the FDA process; rather, it suggests means by which the application might provide a reasonable assurance of safety and efficacy. Id.

The Lohr Court's refusal to accord preemptive effect to more prescriptive, if less device-specific, regulations, further counsels against preemption. As noted above, the Lohr Court declined to give preemptive effect to the MDA's prescriptive labeling and manufacturing regulations (the GMP's), since they are best described as "entirely generic concerns about device regulation generally, not the sort of concerns regarding a specific device or field of device regulation that the statute or regulations were designed to protect from potentially contradictory state requirements."[12/] 518 U.S. at 501. Although the PMA process is obviously device-specific, it is far less prescriptive than the rules relating to labeling and manufacturing. Thus, the Court's preemption analysis suggests that state law claims

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[12/] Defendant argues that these general regulations are made "concretely specific" to its device "as part of the PMA process itself." (Def.'s Reply Mem. at 6.) On this basis, defendant argues that the labeling regulations and GMP's impose specific requirements in the PMA context. Id. However, when the Lohr Court held that those regulations did not preempt state law claims, it expressly contemplated the application and enforcement of the same substantive requirements. 518 U.S. at 497-98. Thus, those regulations failed to receive preemptive effect under Section 360k because they do not impose device-specific requirements, see id. at 498, not because the FDA had not yet taken an enforcement action with respect to a specific device.

should not be trumped. According to the Court, federal action will not preempt state law if the federal government has not "weighed the competing interests relevant to the particular requirement in question, reached an unambiguous conclusion about how those competing considerations should be resolved in a particular case or set of cases, and implemented that conclusion via a specific mandate on manufacturers or producers." Id. PMA approval does not impose an ascertainable "specific mandate;" it represents only the FDA's judgment that a manufacturer has reasonably assured the FDA of the device's safety and effectiveness. Thus, this Court is unwilling to interpret the PMA process as a specific federal requirement sufficient to trigger preemption and protection of a manufacturer from suit.

Defendant attempts to distinguish Lohr from the facts of this case by stressing the factual dissimilarities between the Section 510(k) premarket notice process and PMA review. Defendant argues that the more thorough PMA review for safety and effectiveness means that FDA approval is more likely to establish device-specific requirements that preempt state law. Every court that has considered MDA preemption has noted the significant difference in the degree of scrutiny between Section 510(k) notice review and the PMA process. See, e.g. Martin, 254 F.3d at 578 n.4; Goodlin, 167 F.3d at 1370 n.1; see also Lohr, 518 U.S. at 478-79 ("The § 510(k) notification process is by no means comparable to the PMA process."). It is certainly true that the 510(k) inquiry is much less rigorous than the PMA process: FDA review is completed in an average of 20 hours, as opposed to 1200 for a PMA review. See Lohr, 518 U.S. at 477. However, even if the PMA process is much more rigorous, time-consuming, and expensive, this does not mean that the approval imposes "specific requirements." Furthermore, the Section 510(k) and PMA processes serve the same purposes: "[T]he FDA simultaneously maintains the exhaustive PMA and the more limited § 510(k) processes in order to

ensure both that medical devices are reasonably safe and effective and that, if the device qualifies under the § 510(k) exception, it is on the market within a relatively short period of time." Buckman, 121 S. Ct. at 1018. Standing alone, differences in the degree of regulatory scrutiny are insufficient to distinguish principles announced in Lohr from the instant case: it is the specificity of the regulatory mandate, not the length and cost of review, that is relevant under Section 360k.

Finally, defendant raises the specter that this Court will eviscerate Section 360k by holding that FDA approval imposes no requirements. (Def. Mot. at 25 (citing Kemp, 231 F.3d at 227).) However, this Court's interpretation of "requirement" imposes no insuperable bar to MDA preemption. For example, were the FDA to promulgate a regulatory mandate similar to that suggested by Justice Breyer's two-inch wire example, contrary state law would obviously be preempted. The FDA has apparently chosen not to invoke this authority, and instead, it has

interpreted Section 360k to preempt only "specific counterpart regulations" and other "specific requirements." 21 C.F.R. § 808.1(d).

In sum, because the PMA process neither reveals nor imposes any ascertainable substantive prerequisite for approval, it is not possible for the Court to conduct the "careful comparison" between state and federal requirements that is mandated by Lohr.[13/] 518 U.S. at 500. Nor has defendant pointed to any substantive federal requirement, but instead, it argues solely on the basis that the rigors of the PMA process transform it into a specific federal requirement. Given this Court's rejection of that position, defendant cannot, based on the record before the Court, carry its burden of "demonstrat[ing] that 'there is a conflict between the state and federal regulations of the medical devices which threatens to interfere with a specific federal interest.'" Mitchell, 126 F.3d at 913 (citation omitted).

III. Implied Preemption

Defendant also argues that plaintiffs' claims are impliedly preempted. Federal preemption may be implied from a statute's structure and purpose, or a state law may be preempted if there is an actual conflict with federal law. See Cipollone, 505 U.S. at 516. Defendant relies on Freightliner Corp. v.

[13/] Since the Court has concluded that the PMA approval does not in fact establish any ascertainable requirements that would preempt state tort claims, it need not consider whether state law claims would impose different or additional requirements relating to safety or effectiveness. However, given the Court's analysis regarding "federal requirements," it may well follow that state law claims would also be viewed as too general to be preempted. See 21 C.F.R. § 808.1(d) (the MDA does not preempt "State or local requirements of general applicability where the purpose of the requirement relates . . . to other products in addition to devices"); Lohr, 518 U.S. at 491 (Section 360k was "not intended to pre-empt most, let alone all, general common-law duties enforced by damages actions.") (plurality opinion).

Myrick, 514 U.S. 280 (1995), and Geier v. American Honda Motor Co., 529 U.S. 861 (2000) (ordinary conflict preemption analysis not barred by presence of express preemption and saving clauses), to argue that an implied preemption analysis of the MDA is appropriate. In Freightliner, the Supreme Court held that an express preemption provision does not necessarily foreclose the possibility of implied preemption; at best, the presence of such a provision "supports an inference that an express pre-emption clause forecloses implied pre-emption." Id. at 289 (discussing Cipollone, 505 U.S. 504). Thus, unless Congress intended Section 360k to foreclose an ordinary preemption analysis, this Court should consider whether plaintiff's state-law claims conflict with federal law and are thus impliedly preempted. See Freightliner, 514 U.S. at 287-89.

With respect to the MDA, however, there is no need to look beyond Section 360k to ordinary conflict preemption principles. When there is evidence that Congress considered the issue and an express preemption provision provides a "reliable indicium of congressional intent with respect to state authority, there is no need to infer congressional intent to pre-empt state laws from the substantive provisions of the legislation." Cipollone, 505 U.S. at 517 (citations and internal quotation marks omitted). Obviously Congress considered the preemption issue; it enacted Section 360k as part of the MDA. Additionally, Congress conferred authority on the FDA to implement this provision, see 21 U.S.C. § 360k(b), and the agency did so by promulgating 21 C.F.R. § 808.1. This delegation to the FDA suggests a congressional belief that the particular subject matter of the MDA – medical device regulation – argues for deference to FDA's "special understanding of the likely impact of both state and federal requirements, as well as an understanding of whether (or the extent to which) state requirements may interfere with federal objectives." Lohr, 518 U.S. at 506 (Breyer, J., concurring). Given the

express provision and reliance on informed agency involvement to define the preemptive scope of the MDA, there is no need for this Court to expand the preemptive reach of the MDA beyond Section 360k.

Even if this Court were to undertake a traditional preemption analysis, the result would not change, because plaintiffs' state law claims do not conflict with federal law. Defendant argues that subjecting defendant to the additional or different requirements of state tort regimes would thwart the primary objectives of the MDA.[14/] (Def.'s Mot. at 39). This Court, however, cannot find that plaintiffs' claims "stand[] as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." Hines v. Davidowitz, 312 U.S. 52, 67 (1941). First, as noted above, the MDA does not impose substantive requirements on medical devices through the PMA process. Neither does the MDA prescribe design specifications or specific labels. It is therefore difficult to see how the MDA could preempt plaintiffs' state law claims.

Second, there is no basis upon which to argue that additional or different state requirements would frustrate the congressional aims underlying the MDA. As noted above, the PMA process is one

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[14/] Plaintiff's reliance on Martin v. Telectronics Pacing Systems, Inc., 105 F.3d 1090 (6th Cir. 1997), is misplaced. First, as defendant notes (Def.'s Mot. at 38), Martin is not an implied preemption case, but instead is an application of Lohr to determine the preemptive effect of approval under the Investigational Device Exemption ("IDE") from the PMA process. The Martin court found both that IDE approval did preempt the state manufacturing and design defect claims and that such preemption was consonant with IDE's purpose: "'to encourage, to the extent consistent with the protection of public health and safety and with ethical standards, the discovery and development of useful devices intended for human use.'" Martin, 105 F.3d at 1099 (quoting 21 U.S.C. § 360j(g)). However, because fostering innovation is not as central to the PMA process, as compared to the IDE, and because this Court has already found that the MDA does not expressly preempt plaintiff's claims, Martin is of little assistance.

means by which a medical device manufacturer can provide "reasonable assurance" to the FDA of a devices's safety and efficacy. 21 U.S.C. § 360c(a)(1)(C). The process serves a gatekeeping function, preventing dangerous devices from reaching the market altogether. See Goodlin, 167 F.3d at 1378 (observing that "Congress intended to regulate medical devices *before* they reached consumers, rather than address the consequences once on the market") (emphasis in original). The entire regulatory scheme seeks to assure "minimal safety for public consumption," and its ultimate aim is to provide for "'the safety and effectiveness of medical devices intended for human use.'" Id. at 1378 (quoting Pub.L. No. 94-925, 90 Stat. 539, 539 (1976) (preamble)). Defendant points out that encouraging innovation in the medical device market is also an important goal of the MDA. (Def.'s Mot. at 38-39.) Certainly Congress crafted an exception to the PMA process, the IDE, to achieve this aim. See 21 U.S.C. § 360j(g). However, fostering innovation does not require the elimination of all burdens on medical device manufacturers, and it is not entirely clear why preempting state tort law would advance innovation, except to save manufacturers the expense of litigation when their devices allegedly cause injury. Furthermore, there is no evidence that Congress intended Section 360k to achieve this end. Ultimately, requiring manufacturers to provide a threshold assurance of safety is not inconsistent with post-marketing lawsuits challenging the safety of their devices. Rather, these pre- and post-market mechanisms compliment one another, and together may more effectively safeguard human health.

Given the well-established presumption against preemption of state law, this Court cannot find that the MDA impliedly preempts plaintiffs' state law claims. Accordingly, defendant's motion to dismiss on the grounds of implied preemption is denied.

CONCLUSION

For all of the above reasons, Defendants' Motion to Dismiss or, Alternatively, for Summary Judgment is denied. A separate order will accompany this opinion.

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ELLEN SEGAL HUVELLE
United States District Judge

Dated:

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

ARNOLD W. WEBSTER, *et al.*,	)	
Plaintiffs,	)	
v.	)	**Civil Action No. 01-00928 (ESH)**
PACESETTER, INC.	)	
Defendant.	)	

ORDER

This matter is before the Court on defendants' Motion to Dismiss, or, Alternatively, for Summary Judgment [18-1, 18-2] and plaintiff's opposition thereto. For the reasons stated in the Court's accompanying memorandum opinion, it is hereby

ORDERED that defendants' motion is DENIED as to all counts of plaintiff's complaint; and it is

FURTHER ORDERED that this matter is set for an initial scheduling conference on November 28, 2001, at 9:15 a.m.

SO ORDERED.

Ellen Segal Huvelle
United States District Judge

Dated: